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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,652	03/13/2001	D. Laksen Sirimanne	END-5247USCNT1	4202

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EXAMINER	
SMITH, RUTH S	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/805,652	SIRIMANNE ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26,29-31,33,34,109 and 110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26,29-31,33,34,109 and 110* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/23/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 61,102 of U.S. Patent No. 6,371,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because it involves an obvious broadening of the patented claims. Both claim sets include at least two implantable bioabsorbable bodies and a marker affixed to at least one of the markers. The use of an implantable body that is non-radioactive would have been an obvious selection of known materials for implants.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 110 of copending Application No. 10/114,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 involves an obvious broadening of claim 110. Both claim sets include an implantable body and a marker affixed to the body. The specific material of the implant used would have been an obvious choice of known

equivalents in the art and the number of implants and markers used would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 38 of copending Application No. 10/960,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have carried out the method of claim 38 using the device of claim 1. In view of the recitation of at least one bioabsorbable body in claim 38, it would have been obvious to have provided at least two bodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 109,128,152,177 of copending Application No. 10/960,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to have carried out the method of claims 128,177 using the device of claim 1. In view of the recitation of at least one bioabsorbable body in claims 109,128,152,177, it would have been obvious to have provided at least two bodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

Claims 11-13,26,110 are objected to because of the following informalities: With respect to claims 11,12, it is unclear as to what makes the markers/bodies "mammographic"? It appears that these claims appear to be directed to the use of the markers/bodies only. In claim 13, it is unclear as to what further structural limitation has

been set forth. The claim appears to merely set forth an inherent result of where these bodies are placed. Claim 26 appears to be directed to a method of making the device and fails to set forth an additional structural limitation of the device. Claim 110 appears to be directed only to the intended use of the device. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16,18-26,29-31,33,34,109-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al. Stinson et al disclose a marking device comprising an implantable body and a non-radioactive marker affixed to a surface of or disposed within the implant. The implant can comprise a bioabsorbable material (column 14, lines 65-67) which is non-radioactive. Applicant's attention is invited to In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) where the court held that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. It would have been obvious to one skilled in the art to have provided a plurality of separately implantable bodies such that the procedure can be conducted

more than a single time or if the first implantable body is defective a second one can be used. The marker of Stinson et al can comprises the materials set forth in claims 3,6-7. With respect to claims 8,18,28, in the absence of any showing of criticality, the specific material used to provide the bioabsorbable body would have been an obvious design choice of known equivalents in the art. With respect to claims 9-12, the specific material used for the marker to make it visible would have been obvious to one skilled in the art based upon the type of imaging modality used. With regard to claim 16, it is a well-known expedient in the medical art to provide a pain killing substance in combination with a therapeutic procedure so as to reduce the pain that the implantation can cause. Therefore, it would have been obvious to one skilled in the art to have provided a pain killing substance to the patient in order to make the procedure less uncomfortable. The marker can be in the form of a wire, or suture. With regard to claims 19-21,25, in the absence of any showing of criticality, the specific shape of the marker used would have been an obvious design choice of known equivalents in the art. Claim 26 is considered to be a product-by-process claim and the manner in which the product is made fails to impose any further structural limitations on the claim. With regard to claims 29, 30, in the absence of any showing of criticality, the specific shape of the bioabsorbable body would have been an obvious design choice of known equivalents. With regard to claim 31, In the absence of any showing of criticality, the specific shape of the implant would have been an obvious design choice of known equivalents. With regard to claims 33,34, the braid-like configuration of the implant is considered to include pores that will promote tissue in growth. With respect to claim 109, the material of the implant is considered to be resilient.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson et al as applied to claim 1 above, and further in view of Good (6,666,811). Stinson et al fails to disclose the use of a hemostatic material. Good discloses an implantable body including a hemostatic material enabling it to be easily implanted in the tissue. It would have been obvious to one skilled in the art to have modified Stinson et al such that it includes a hemostatic material which enhances its ability to be implanted in the body.

Response to Arguments

Applicant's arguments with respect to claims 1-31,33,34,109-110 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS